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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,190	02/28/2002	Pia M. Challita-Eid	511582003420	7796

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,190	CHALLITA-EID ET AL.	
	Examiner	Art Unit	
	David J Blanchard	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 4-7,9-13,15,19-21,48,49,54,65-70 and 78-82 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 4-7,9-13,15,19-21,48,49,54,65-70 and 78-82 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 4-7, 9-10, 12-13 and 78-82, drawn to an antibody that binds SEQ ID NO:2, classified in class 530, subclass 387.9.

II. Claim 11, drawn to a non-human transgenic animal that produces an antibody that specifically binds SEQ ID NO:2, classified in class 800, subclass 6.

III. Claim 15, drawn to a method of delivering an agent to a cell expressing SEQ ID NO:2 with the antibody of claim 4, classified in class 424, subclass 178.1.

IV. Claims 19-21, drawn to an immunogenic composition comprising an immunogenic portion of SEQ ID NO:2, classified in class 530, subclass 300. See item #2 below.

V. Claims 48-49, drawn to a method of inhibiting the growth of cancer cells with an antibody that binds SEQ ID NO:2, classified in class 424, subclass 138.1.

VI. Claim 54, drawn to a method of inhibiting the growth of cancer cells comprising administering human T cells, classified in class 424, subclass 93.1.

VII. Claims 65-66 in part and claims 68-69, drawn to a method of activating a cytotoxic T cell with an immunogenic portion of SEQ ID NO:2 wherein said immunogenic portion comprises a T cell epitope, classified in class 424, subclass 185.1.

VIII. Claims 65-66 in part and claim 67, drawn to a method of inducing a B cell to generate antibodies with an immunogenic portion of SEQ ID NO:2 comprising at least one B cell epitope wherein the antibodies bind said B cell epitope, classified in class 435, subclass 69.6.

IX. Claims 65-66 in part and claims 68-69, drawn to a method of activating a cytotoxic T cell with a nucleotide sequence that encodes an immunogenic portion of SEQ ID NO:2 wherein said immunogenic portion comprises a T cell epitope, classified in class 424, subclass 185.1.

X. Claims 65-66 in part and claim 67, drawn to a method of inducing a B cell to generate antibodies with a nucleotide sequence that encodes an immunogenic portion of SEQ ID NO:2 comprising at least one B cell epitope wherein the antibodies bind said B cell epitope, classified in class 435, subclass 69.6.

XI. Claim 70, drawn to an assay for detecting expression levels of 121P1F1 (SEQ ID NO:2) in a cancer patient with an antibody that binds SEQ ID NO:2, classified in class 435, subclass 7.1.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121. If the Invention of Group IV is elected, Applicant is required to further elect ten CTL peptides listed in Tables V-XVIII, XXVI, and XXVII. It is noted that some of the claimed tables do not appear to comply with the sequence rules because they contain sequences that do not have sequence identifiers (see Tables V(A) and VI(A), for example). Applicant is reminded that all sequences must comply with the sequence rules, 37 C.R.F. §§ 1.821-1.825.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-II and IV represent separate and distinct products, which are made by materially different methods, and are used in materially different methods, which have different modes of operation, different functions and different effects. The antibody of Group I, the non-human transgenic animal of Group II and the immunogenic composition of Group IV are all structurally and chemically different from each other. The antibody of Group I is raised by immunization, the non-human transgenic animal is made by gene targeting and the polypeptide composition of Group IV is made by translation of mRNA. Furthermore, the antibody can be used to purify the antigen, the non-human transgenic animal can be used produce recombinant proteins, and the polypeptide composition can be used as an antagonist. The polypeptides of Groups V-XVIII, XXVI and XXVII are patentably distinct because each is structurally distinct and art on one would not necessarily be art on the others. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature

and would require the consideration of different patentability issues. Thus, the inventions I, II and IV are patentably distinct.

The methods of Inventions III and V-XI differ in the method objectives, method steps and parameters and in the reagents used. Invention III recites a method of delivering an agent to a cell expressing SEQ ID NO:2 with the antibody of claim 4; Invention V recites a method of inhibiting the growth of cancer cells with an antibody that binds SEQ ID NO:2; Invention VI recites a method of inhibiting the growth of cancer cells comprising administering human T cells; Invention VII recites a method of activating a cytotoxic T cell with an immunogenic portion of SEQ ID NO:2 wherein said immunogenic portion comprises a T cell epitope; Invention VIII recites a method of inducing a B cell to generate antibodies with an immunogenic portion of SEQ ID NO:2 comprising at least one B cell epitope wherein the antibodies bind said B cell epitope; Invention IX recites a method of activating a cytotoxic T cell with a nucleotide sequence that encodes an immunogenic portion of SEQ ID NO:2 wherein said immunogenic portion comprises a T cell epitope; Invention X recites a method of inducing a B cell to generate antibodies with a nucleotide sequence that encodes an immunogenic portion of SEQ ID NO:2 comprising at least one B cell epitope wherein the antibodies bind said B cell epitope; Invention XI recites an assay for detecting expression levels of 121P1F1 (SEQ ID NO:2) in a cancer patient with an antibody that binds SEQ ID NO:2. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability

issues. Thus, inventions III and V-XI are separate and distinct in having different method steps and different endpoints and are patentably distinct.

Inventions I and (III, V and XI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group I can be used in a materially different method such as to purify the antigen in addition to the materially different methods of Group III, V and XI.

Inventions IV and (VII and VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the immunogenic polypeptide portion of SEQ ID NO:2 of Group IV can be used in a materially different method such as an antagonist in addition to the materially different methods of Groups VII and VIII.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The official fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827

LARRY R. HELMS, PH.D
PRIMARY EXAMINER